K071204

BARD
Bard Access Systems

MAY 18 2007

Site~Rite® 6 Ultrasound System
510(k) Summary

Device trade name: Site~Rite® 6 Ultrasound System

Device class and panel: Class II, 21 CFR §892.1560, Ultrasonic Pulsed Echo Imaging System, 90IYO
Class II, 21 CFR §892.1570, Diagnostic Ultrasonic Transducer, 90ITX

Applicant name: Kimberly Geisler
Bard Access Systems, Inc. [wholly owned subsidiary of C.R. Bard, Inc.]
5425 West Amelia Earhart Drive
Salt Lake City, UT 84116
(801) 595-0700, x5421 (phone)

Predicate device: K052517, Site~Rite® 5 Ultrasound System

Performance Standards: Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Indications for Use: The Site~Rite® 6 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.

Device description: The Site~Rite® 6 Ultrasound System is a lightweight, low-output, real-time B-mode ultrasonic pulsed echo imaging system designed primarily to assist physicians in gaining vascular access to major veins and arteries. The Site~Rite® 6 Ultrasound System is portable and therefore easy to use at the bedside and in a variety of clinical scenarios, including intensive care units, emergency rooms, operating rooms, angiography suites, catheterization laboratories, etc. In addition, the Site~Rite® 6 Ultrasound System is designed with simple operating controls to facilitate easy operation.

Technological Characteristics: Technological similarities between the subject Site~Rite® 6 Ultrasound System and the predicate device remain identical. There are no new questions raised regarding safety or efficacy of the Site~Rite® 6 Ultrasound System.

Safety & Performance Tests: Verification and validation tests have been performed in accordance with Design Controls per 21 CFR 820.30.

Summary of Substantial Equivalence: Based on the indications for use, technological, and safety and performance testing, the subject Site~Rite® 6 Ultrasound System meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, material, principles of operation and indications for use to the current commercially available Site~Rite® 5 Ultrasound System.

®Site~Rite is a registered trademark of C.R. Bard, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2007

Ms. Kimberly Geisler
Regulatory Affairs Specialist
C.R. Bard, Inc.
Bard Access Systems, Inc.
5425 West Amelia Earhart Drive
LAKE CITY UT 84116

Re: K071204
Trade Name: Site~Rite® 6 Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: April 30, 2007
Received: May 1, 2007

Dear Ms Geisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Site~Rite® 6 Ultrasound System, as described in your premarket notification:

Transducer Model Number

Site~Rite 6

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

1.2 Indications for Use Statement

510(k) Number (if known): K071204

Device Name: Site~Rite® 6 Ultrasound System

Indications for Use:

The Site~Rite® 6 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071204

Site~Rite® 6 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Intraoperative (epiaortic scanning)

Small organ (breast, testes, thyroid, etc.)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use (Per 21 CFR §801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K071204

Site~Rite® 6 Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (specify)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

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(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use (Per 21 CFR §801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071204